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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,734	01/20/2004	Lior Gepstein	27395	7379

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EXAMINER

HAMA, JOANNE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/759,734

Applicant(s)

GEPSTEIN ET AL.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-195 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-195 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

This Application, filed January 20, 2004, is a CIP of PCT/IL02/00606, filed July 21, 2002, which claims benefit of 60/306,462, filed July 20, 2001.

Claims 1-195 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-99, drawn to a method of generating cells or tissue predominantly displaying at least one characteristic associated with a cardiac phenotype, classified in class 435, subclass 377.
2. Claims 100-141, drawn to a method of qualifying the effect of a treatment on a biological state or a biological process of cardiac cells or cardiac tissue, classified in class 435 subclass 377.
3. Claims 142-175, drawn to a method of repairing cardiac tissue in a subject, classified in class 424, subclass 93.21.
4. Claims 176-195, drawn to an *in vitro* culture of human cells which display proliferation and at least one characteristic associated with a cardiac phenotype, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4 are distinct. While there is a common thread of an *in vitro* culture of human cells that display proliferation and at least one characteristic associated with a cardiac phenotype (Invention 4) amongst the inventions, Invention 4 can be used in different and distinct methods (Inventions 1-3), each of which has different steps and

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each of which expect different outcomes. The search and examination of Inventions 1-4 is burdensome because the searches are not coextensive.

The Inventions are further restricted as follows.

Inventions 1-4 comprise distinctly named characteristics that are used to identify a cardiac phenotype in claims 6, 21, 33, 48, 60, 82 of Invention 1, claims 106, 124 of Invention 2, claims 147, 166 of Invention 3, claims 177, 189 of Invention 4. One phenotype must be elected for examination. Each of these characteristics is distinct because different methods are used to detect each of these phenotypes. The search and examination of each of these phenotypes are burdensome because the searches are not coextensive.

Invention 1 and Invention 2 comprise distinctly named treatments used to effect a biological state or process in claims 67 and 71 of Invention 1 and claims 109 and 113 of Invention 2 and one must be elected for examination. Each of the treatments is distinct because each requires different reagents and different method steps. The search and examination of each treatment is burdensome because the searches are not coextensive.

Should Invention 1 or Invention 2 and "drug" of claim 67 of Invention 1 or claim 109 of Invention 2 be elected, distinctly named drugs in claim 68 of Invention 1 and claim 110 of Invention 2 are distinct and one must be elected for examination. Each drug is distinct because each has a distinct structure and distinct biological activity. The search and examination for each drug is burdensome because the searches are not coextensive.

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Should Invention 1 be elected, specifically named biological states or biological processes in claim 89 are distinct and one must be elected for examination. Each biological state or biological process is distinct because different methods are used to detect each of these phenotypes. The search and examination of each of these phenotypes are burdensome because the searches are not coextensive.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) and have acquired a separate status in the art in view of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

Should "ion" of claim 67 of Invention 1 and claim 109 of Invention 2 be elected, distinctly named ions in claim 69 of Invention 2 or claim 111 of Invention 2 must be elected for examination. Each ion is distinct because each has a distinct structure and distinct biological activity. The search and examination for each ion is burdensome because the searches are not coextensive.

Claims 22, 49, 83, 90 of Invention 1, claims 125, 132 of Invention 2 are drawn to distinctly named cardiac specific mechanical contraction and one must be elected. Each of the mechanical contractions is distinct from each other because each mechanical contraction requires different mechanisms such that the contraction occurs.

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The search and examination for each mechanical contraction is burdensome because the searches are not coextensive.

Claims 23, 50, 84, 91 of Invention 1, claims 126, 133 of Invention 2, are drawn to distinctly named cardiac specific structures and one must be elected. Each of the structures is distinct because each has a different function in the cell. The search and examination for each structure is burdensome because the searches are not coextensive.

Claims 24, 51, 85, 92 of Invention 1, claims 127, 134 of Invention 2, are drawn to distinctly named cardiac specific RNA that encodes a protein. Each encoded protein is unique because each has a unique structure and unique biological activity. The search and examination for each RNA is burdensome because the searches are not coextensive.

Claims 25, 52, 86, 93 of Invention 1, claims 128, 135 of Invention 2 are drawn to distinctly named cardiac specific protein. Each protein is unique because each has a unique structure and unique biological activity. The search and examination for each protein is burdensome because the searches are not coextensive.

Claims 26, 53, 87, 94 of Invention 1, claims 129, 136 of Invention 2 are drawn to distinctly named electrical activities. Each electrical activity is unique because each requires a different mechanism by which the electrical activity is propagated. The search and examination for each electrical activity is burdensome because the searches are not coextensive.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently,

claims 1-99 of Invention 1, claims 100-141 of Invention 2 are generic for cardiac specific mechanical contraction;

claims 1-99 of Invention 1, claims 100-141 of Invention 2 are generic for cardiac specific structures;

claims 1-99 of Invention 1, claims 100-141 of Invention 2 are generic for cardiac specific RNA that encodes a protein;

claims 1-99 of Invention 1, claims 100-141 of Invention 2 are generic for cardiac specific protein;

claims 1-98 of Invention 1, , claims 100-140 of Invention 2 are generic for electrical activities.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'AMW', with a long horizontal line extending to the right.